PATENT
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

PATENT APPLICATION: DALE R. LOVERCHECK

Serial No. 09/900,647 Art Unit:1617

Filed: July 7, 2001 Examiner: Hui, San Ming R.

For: UNIT DOSE OF MATERIAL IN SYSTEM AND METHOD

The Commissioner for Patents
Alexandria, Virginia. 22313-1450

SUPPLEMENTAL REMARKS

Appellant's invention provides a unit dose of discomfort reliever and nutritional supplement in an enclosure having indications indicating supplementing nutrition. Appellant's invention solves the problems of the prior art of trying to routinely remember to find and consume vitamins and minerals, needing to know when vitamins and/or minerals are being taken in a discomfort reliever and the nutritional sufficiency of the amount taken. It provides superior results in savings of cost, time and storage space, with the same discomfort relief and the same ability to self regulate nutritional supplements, but with half as many unit doses and containers compared to the separately enclosed intended discomfort relievers and intended nutritional supplements of the prior art. One unit dose in one container replacing two unit doses in two containers are data of superior results provided by Appellant's invention. Thus, patentability is shown beyond the requirements of the statute, Demace.

Prior art discomfort relievers and nutritional supplements intended to supplement nutrition are separately sold, disclosed and mandated in distinctively labeled containers. Prior art intended discomfort relievers and intended nutritional supplements are separate unit doses in separate containers, such as those in Table VI, center and right columns, pages 30-31, , pages 1 (last paragraph), 2 (first

paragraph) and 29-32 of the above captioned patent application. For example, major commercial pain relievers (Advil, Motrin, Aleve, Tylenol, Excedrin, and Bufferin: EXHIBITS A-G of the Amendment filed March 1, 2004) are sold in separate unit doses in separate distinctively labeled containers from nutritional supplements (One A Day Maximum multiple vitamin and mineral nutritional supplement packaging: Exhibit B). Labeling for major commercial pain relievers have a listing under Drug Facts, and do not have a listing of Supplement Facts (EXHIBITS A-G of the Amendment filed March 1, 2004). By contrast, labeling for nutritional supplements have a listing under Supplement Facts, and do not have a listing of Drug Facts (One A Day Maximum multiple vitamin and mineral nutritional supplement packaging: Exhibit B). Thus, prior commercial intended discomfort reliever products and intended nutritional products are separate products enclosed in separate distinctively labeled containers.

Dietary supplements are products intended to supplement the diet that contain a vitamin or mineral (EXHIBIT E of the April 1, 2004 Amendment). SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose supplementing nutrition. So, any supplementing of nutrition is unintended in products based on SS Pharmaceutical, Tsunoda, and Yeh et al. Thus SS Pharmaceutical, Tsunoda, and Yeh et al do not disclose intended nutritional supplements. Only products intended as drugs are disclosed by SS Pharmaceutical, Tsunoda, and Yeh et al. Krause discloses products intended as processed food. So, intended discomfort relievers and intended nutritional supplements are separately disclosed in the applied prior art. Intended discomfort relievers and intended nutritional products are separate products in separate containers, pages 1 (last paragraph), 2 (first paragraph) and 29-32 of the above captioned patent application. For example, major commercial pain relievers (Advil, Motrin, Aleve, Tylenol, Excedrin, and Bufferin: EXHIBITS A-G of the Amendment filed March 1, 2004) are sold in separate unit doses in separate distinctively labeled containers from nutritional supplements (One A Day Maximum multiple vitamin and mineral nutritional supplement packaging: Exhibit B). So, the separately disclosed intended discomfort relievers of SS Pharmaceutical, Tsunoda, and Yeh et al and intended foods of Krause would be made as separate products,

that would be enclosed in separate distinctively labeled containers.

Prior art discomfort relievers and nutritional supplements intended to supplement nutrition are separately mandated. Drug labeling law does not refer to nutrition labeling. Similarly, nutrition labeling law does not refer to drug labeling. Furthermore, the sample drug labels do not mention nutrition information, (21 CFR 201.66-Exhibit G of the Amendment filed March 1, 2004). And, the sample nutrition labels do not mention drug information, (21 CFR 101.9 (c)(12-14) and 21 CFR 101.36 (e)(10)-Exhibit D, parts 1 and 2 of the Amendment filed May 11, 2004). So, the law has not mentioned or mandated nutritional labeling of drugs, containing vitamins and minerals which are not provided for supplementing nutrition.

Appellant's invention omits one unit dose and container of two of the prior art with retention of their functions. These are indicia of unobviousness, In re Edge. The indications that support the superior results are not expected because they are not required by drug law, they are not disclosed in SS Pharmaceutical, Tsunoda, and Yeh et al, and the combination of these references with Krause is improper.

The combination of SS Pharmaceutical, Tsunoda, Yeh et al in view of Krause is improper because nothing is mentioned or taught in them to suggest their combination, In re Sernaker. The Examiner has made legally erroneous use of the inventor's patent specification teaching of both a novel and nonobvious invention as though it were prior art in order to make claims appear to be obvious In re Pleuddemann.

For a vitamin or mineral in a drug product to be a nutritional supplement it must be intended to supplement nutrition, because, dietary supplements are products intended to supplement the diet that contain a vitamin or mineral (Dietary Supplement Health and Education Act of 1994 Section 3 (a)(ff) (1) Nutritional Supplements Association page 3: EXHIBIT E of the April 1, 2004 Amendment). So, synergistic antioxidant vitamin C is not a nutritional supplement in products of SS Pharmaceutical, Tsunoda, and Yeh et al, because it is not intended to supplement the diet.

The reference daily intake of vitamin C is an amount (60 milligrams)

needed for nutrition, as see Krause pages 277-278 and 21 CFR 101.9: Exhibit D, part 1. Percent daily value is determined from this amount (21 CFR 101.36 (b)(iii)(B). Yeh et al do not disclose nutrition on any specific amount of any antioxidant. Yeh et al only disclose a percent of antioxidant relative to other ingredients column 4, lines 4-11. Similarly, Tsunoda only discloses synergist vitamin C relative to other ingredients, and does not disclose nutrition. Whereas, for nutrition an amount (60 milligrams) of vitamin C is needed daily. Thus, Yeh et al and Tsunoda teach away from Appellant's invention by teaching a percent of antioxidant only relative to other ingredients. Also, Yeh et al teach away from Appellant's invention by teaching that the lack of anything that could function as a nutritional supplement is suitable for its purposes. Furthermore, in Yeh et al the proportion of antioxidant is based on arylpropionic NSAID to reduce disease, column 4, lines 4-11. This teaches away from the claimed invention wherein nutritional supplements are provided to supplement nutrition. Portions of a reference teaching away from the claimed invention must be considered, Bausch & Lomb Inc v Barnes-Hind/Hydrocurve, Inc, 796 F2d 443; 230 USPQ 416 (CAFC 1986).

The Examiner states that there is no evidence of others working on the problem (page 2 of the Advisory action dated May 8, 2004). Vitamins and minerals are essential to good health, and knowing whether we are sufficiently consuming them is a problem that is partially solved by guidelines of recommended daily amounts, (Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, page 17: EXHIBIT A). This is objective evidence that the art recognized that consumers need to know the sufficiency of their consumption of intended nutritional supplements MPEP 716.04. Prior art nutritional supplements, such as those in Table VI, center column pages 30-31 of the above captioned patent application, are objective evidence that the art recognized a need for their consumption, MPEP 716.04. The evidence indicates that for many people there has been a long felt need for regular use of nutritional supplements, see page 1, last paragraph of the above captioned patent application, COUNCIL FOR RESPONSIBLE NUTRITION, The Benefits of Nutritional Supplements,

Executive summary 2001. This is objective evidence that the art recognized a need for regular consumption of nutritional supplements, MPEP 716.04. Thus, the need for regular use of nutritional supplements is a known problem. Prior art problems of regular use include routinely remembering to take nutritional supplement pills, knowing when vitamins and minerals are being consumed, and knowing the sufficiency for nutritional needs of the vitamins and minerals are being consumed.

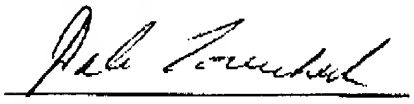
The Examiner states that vitamin C is a nutritional supplement, (pages 2 and 3 of the Advisory action dated May 8, 2004). But, for a vitamin or mineral in a drug product to be a nutritional supplement it must be intended to supplement nutrition, because, dietary supplements are products intended to supplement the diet that contain a vitamin or mineral (Dietary Supplement Health and Education Act of 1994 section 3 (a)(ff) (1) Nutritional Supplements Association page 3: EXHIBIT E of the April 1, 2004 Amendment). For example, nutritional supplements include calcium, magnesium and iron, (Lieberman and Bruning, The Real Vitamin and Mineral Book, 1997, pages 138, 146 and 157: EXHIBIT A). And, Advil, Motrin and Bufferin commercial pain relievers contain calcium, magnesium and iron in their buffering agents and inert ingredients (Exhibits A, B and G of the Amendment filed March 1, 2004). Yet, no nutrition information is included in Advil, Motrin or Bufferin pain reliever packaging. So, when minerals are not provided for supplementing nutrition, the law does not mandate nutritional indications for them in drugs. Thus, it was not obvious or mandatory to include any nutrition information in labeling Advil, Motrin and Bufferin commercial pain relievers (Exhibits A, B and G of the Amendment filed March 1, 2004). Accordingly, the law has not made obvious or necessary the inclusion of indications for supplementing nutrition for vitamin C, when used without any intention of supplementing nutrition, as an antioxidant and/or synergistically for pain relief.

The Examiner states that the law mandates the inclusion of indications, (page 3 of the Advisory action dated May 8, 2004 and pages 5 and 7 of the Final Rejection). But, drug labeling law does not refer to nutrition labeling. Similarly,

nutrition labeling law does not refer to drug labeling. Furthermore, the sample drug labels do not mention nutrition information (21 CFR 201.66-Exhibit G of the Amendment filed March 1, 2004). And, the sample nutrition labels do not mention drug information, (21 CFR 101.9 (c)(12-14) and 21 CFR 101.36 (e)(10)-Exhibit D, parts 1 and 2 of the Amendment filed May 11, 2004). So, the law has not mentioned or mandated nutrition labeling of drugs, containing vitamins and/or minerals which are not provided for supplementing nutrition.

Antioxidant vitamin C, as a preservative antioxidant to reduce oxidation of a drug medication, may be exempted from labeling under 21 CFR 201.117, (EXHIBIT C) in products based on SS Pharmaceutical, Tsunoda, and/or Yeh et al. So, putting information about it on the label is not mandated by law. Also, synergistic antioxidant vitamin C may be labeled as part of a drug medication, under 21 CFR sections 201.57 and 201.60 to 201.66 in products based on SS Pharmaceutical, Tsunoda, and/or Yeh et al. Since, they do not disclose supplementing nutrition, putting information about supplementing nutrition on the label is not mandated by law. And, assuming that the authors and inventors knew that vitamin C can be a nutritional supplement, they knowingly did not disclose supplementing nutrition. Accordingly, no nutrition information would be mandated to be included in labeling products based on SS Pharmaceutical, Tsunoda, and/or Yeh et al.

Respectfully submitted,



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